Remarks

The July 6, 2009 Official Action and the references cited therein have been carefully reviewed. In view of the amendments presented herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set forth in the July 6, 2009, Official Action. Therefore, the initial due date for response was October 6, 2009. This response is being filed with a petition for a three (3) month extension of time.

As a preliminary matter, Applicants note that the Examiner has again deemed the restriction requirement proper and made it final. Accordingly, claims 6-7, 41-43, 47, and 49 are currently under examination and claims 3-5, 8-13, 15-40, 44-46, 48, and 50 have been withdrawn from consideration. The previous grounds of rejection have been withdrawn in view of Applicant's prior amendments to the claims; however, the Examiner has raised three new grounds of rejection.

Turning to the substantive aspects of the Official Action, at page 3 the Examiner has rejected claims 6 and 7 under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. In response, Applicants have amended claim 6 in line 3 to recite "individual" as opposed to "subject", thereby providing proper antecedent basis from claim 47 and rendering the rejection moot. Claim 7 has also been amended to include specific SEQ ID NOs for the recited peptide sequences, thereby obviating this aspect of the rejection.

Claims 6-7, 41-43 and 47 now stand rejected under 35 U.S.C. §112, first paragraph for lack of enablement

The Examiner has also rejected claims 1-2, 6-7, 41-43, 47 and 49 as allegedly anticipated by the disclosure in U.S. Patent 6,642,008 (of record) as evidenced by Dukers et al. (2000, of record) and Wakiguchi et al. (Crit. Rev. Oncol.

Hemat. 44 (2002) 193-202).

Applicants respectfully submit that the claims as instantly presented are in condition for allowance. Each of the above-noted objections and rejections under 35 U.S.C. §112, and §102 is, therefore, respectfully traversed.

CLAIMS 6-7, 41-43 and 47, AS AMENDED, FULLY SATISFY THE ENABLEMENT REQUIREMENTS OF 35 U.S.C. §112, FIRST PARAGRAPH

At page 3 of the Official Action, the Examiner newly asserts that the subject matter encompassed by claims 6-7, 41-43 and 47 is not enabled by the specification. More specifically, it is the Examiner's position that the disclosure in the specification is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation.

Applicants respectfully disagree with the Examiner's position regarding the enablement rejection. However, in the sole interest of expediting prosecution in the instant application, and without acquiescing to the Examiner's characterization of inducing "tolerance" as encompassing completely preventing any response to the antigen, Applicants have amended claim 47 to recite that the method inhibits the immune response to the target antigen.

In light of the instant amendment to claim 47, Applicants respectfully submit that the skilled artisan could readily practice the invention encompassed by the claims without undue experimentation. In re Wands, 8 U.S.P.Q.2d 1400, 1404 (1988). Accordingly, the rejection of the claims under 35 U.S.C. §112, first paragraph is untenable and should be withdrawn.

CLAIMS 6-7, 41-43, 47 AND 49 ARE NOT ANTICIPATED BY THE REFERENCES CITED BY THE EXAMINER

The Examiner has rejected claims 1-2, 6-7, 41-43, 47 and 49 under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent 6,642,008 (of record) as evidenced by Dukers et al. (2000, of record) and Wakiguchi et al. (Crit. Rev. Oncol.

Hemat. (2002) 44:193-202). Applicants note that claims 1-2 have been cancelled, and their inclusion in the rejection appears to be an error.

The '008 Patent teaches administering EBV-encoded LMP1 protein to a subject seropositive for EBV for the purpose of targeting cells harboring latent virus for destruction. Dukers et al. disclose LMP protein sequences. It is the Examiner's position that the '008 Patent teaches that LMP1 can be utilized as a fusion with other EBV proteins, and that immune response to EBV viral antigens correlates with atopic disease. The Examiner cites Wakiguchi for the alleged teaching that mosquito allergy is associated with EBV, and concludes that EBV target antigens in the '008 Patent are inherently antigens which "provoke" an allergic immune response thereby anticipating the claims.

Applicants respectfully submit that the rejection under §102(e) is not warranted in this case because the '008 Patent does not disclose an identical invention to that instantly claimed. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990); MPEP §2131 and cases therein (discussing the "every element" rule). More specifically, claim 47, from which all the other remaining claims depend, requires that expression of the tolerogenic peptide sequence (e.g., LMP1 or LMP2 sequence) **inhibit** the immune response to a target antigen, e.g., induce tolerance. The Examiner has not considered this claim feature in making the instant rejection. In every instance, the objective of the methods disclosed in the '008 patent is to elicit production of antibodies to the latent viral proteins or to induce an immune response which is sufficient to kill latently infected cells via the administration of an immunogenic fusion protein. See the abstract. Clearly this patent does not provide a method for inhibiting an immune response to a target antigen and thus does not anticipate the invention.

Applicants agree that the '008 patent teaches fusion proteins. However, the fusion partners are either "large

enough to ***confer immunogenicity*** to the target sequence", e.g., provoke an immune response (column 15, lines 40-45) or protein moieties useful for purification of recombinantly expressed LMP-2A. The vaccines described in the '008 patent and included in the description at column 15 are used "to induce an immune reaction by the host to kill the infected cells". See column 4, lines 60-67. An exemplary molecule is a "chimeric protein consisting of multiple epitopes from one or more latent viral proteins (which) can be use to generate a more immunogenic molecule for administration as a vaccine." Thus, fusions contemplated in this purpose for generating a "***more immunogenic molecule***" rather than a molecule which induces tolerance or inhibits the immune response specific for a target antigen. This teaching cannot be ignored. The Examiner also cites column 22 for teaching a fusion of maltose binding protein and LMP-2A. In construct 1, Harley et al. disclose "Separating the maltose binding protein and LMP-2A is a run of 20 arginines and a Factor Xa cleavage site. The Factor Xa cleavage site allows the LMP-2A peptide to be separated and isolated from the maltose binding protein moiety". MBP is never described as a "target antigen" for which induction of tolerance or inhibition of an immune response desired. Indeed, as taught at column 23, "rabbits immunized with MBP truncated LMP-2A fusion protein generated antibodies that recognize LMP-2A. Notably, Harley et al. are silent regarding inhibiting an immune response against MBP. Clearly, inasmuch as the administered fusion protein "provoked an antibody response" and the vaccines are disclosed as useful for inducing an immune reaction in the host to kill infected cells, Harley et al. explicitly teach away from doing what Applicants have done.

Additionally, the Examiner has cited Wakiguchi et al. in support of her assertion that mosquito allergy is associated with EBV (i.e., EBV is an antigen which provokes an allergic immune response), presumably to address the claim language that the condition is "mediated by an immune response against

the target antigen." However, as evidenced by Ishihara et al., (Int. J. Hematol. (2000) 72:223-228; enclosed herewith), hypersensitivity to mosquito bites is not an allergic disease; rather it is an EBV-associated lymphoproliferative disorder mediated by NK cell lymphocytosis. Inasmuch as the references relied on by the Examiner do not an identical method, the instant rejection is untenable and cannot be maintained.

It appears that the Examiner making an inherency argument at page 6 of the Official Action. However, the Examiner is reminded that "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (P.T.O. B.P.A.I. 1990)(emphasis in original). In other words, inherent anticipation requires inevitability. To be inherent the result must be inevitable from the disclosure or the inherent characteristic must undeniably be present in the invention. *Pingree v. Hull*, 518 F.2d 624, 627 (C.C.P.A. 1975) (declaring "where support must be based on an inherent disclosure, it is not sufficient that a person following the disclosure might obtain the result … it must inevitably happen"). Here the combined teachings of Harley et al. Dukers et al. and Wakiguchi do not anticipate the presently claimed methods since Harley et al. teach methods for inducing an immune response and mosquito allergy is not a condition mediated by an immune response against a target antigen. That being the case, it cannot be reasonably maintained that these references teach a method of which necessarily and invevitably results in **inhibition of** an immune response against a target antigen of interest.

Inasmuch as the '008 patent fails to teach each and every element of the instantly claimed invention and Wakiguchi et al. fails to rectify this deficiency in light of Ishihara et al., Applicants respectfully request the withdrawal of the rejection of claims 6-7, 41-43, 47 and 49 under 35 U.S.C.

§102(e).

CONCLUSION

In view of the present claim amendments, and the foregoing remarks, it is respectfully urged that the rejections set forth in the July 6, 2009, Official Action be withdrawn and that this application be passed to issue. No new matter has been introduced into this application by reason of any of the amendments presented herewith. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
DANN, DORFMAN, HERRELL AND SKILLMAN
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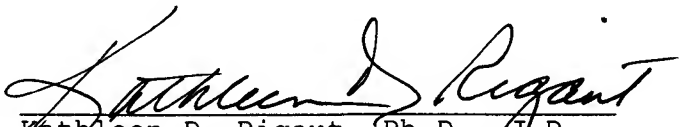
By 
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Enclosure: Ishihara et al., Int. J. Hematol. (2000) 72:223-228